



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,704	11/24/2003	William H. Eby	1421-137	5378

32905 7590 01/03/2005

JONDLE & ASSOCIATES P.C.
9085 EAST MINERAL CIRCLE
SUITE 200
CENTENNIAL, CO 80112

EXAMINER

ROBINSON, KEITH O NEAL

ART UNIT	PAPER NUMBER
----------	--------------

1638

DATE MAILED: 01/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/720,704	EBY ET AL.	
	Examiner	Art Unit	
	Keith O. Robinson, Ph.D.	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claims 1, 2, 7, 12, 14, and 16 are objected to for their inclusion of blanks (____).

It is assumed that the blanks will be replaced by an ATCC Accession Number.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are drawn to seed of soybean variety S030010, methods of using said soybean seed, and parts thereof.

Since the seed is essential to the claimed inventions, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a deposit of the plant. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily available to the public. Thus, a deposit is required for enablement purposes. A deposit of 2500 seed of each of the claimed embodiments is considered sufficient to ensure

Art Unit: 1638

public availability. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see 37 C.F.R. 1.807) and,
- (e) the deposit will be replaced if it should ever become inviable.

It is acknowledged that Applicant has provided a deposit statement in the instant specification (see page 32, paragraph 0149); however, it is incomplete. There is no

Art Unit: 1638

reference regarding the period of time the deposit is to be maintained, no reference to any test of viability of the biological material, nor is there any reference regarding the replacement of the deposit if it becomes inviable.

Claims 7, 9-11, 13-17, 20-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claim 7 is broadly drawn to a soybean plant regenerated from the tissue culture of regenerable cells of soybean variety S030010 wherein said plant is "capable of" expressing the morphological characteristics of soybean variety S030010. Since it is unclear whether the plant actually expresses these characteristics, the claim encompasses tissue-culture-derived somaclonal variants of soybean variety S030010, with mutations at one or more loci, which would not possess all the morphological and physiological traits that are inherent in soybean variety S030010. The specification, however, does not give a written description of such a regenerated plant as to its genetic, morphological, and/or physiological characteristics.

Claims 9-11, 13, 15, and 17 are broadly drawn to hybrid soybean plants derived from the crossing of soybean variety S030010 with any other soybean plant and the seed and plants derived from such a cross. Claims 9-10 are broadly drawn to any hybrid soybean seed or plant, respectively, produced from such a cross. Claim 11 is drawn to

Art Unit: 1638

an F2 plant with, at most, 25% of its genome being derived from the soybean variety S030010. The claims seem to infer any soybean plant will be crossed with soybean variety S030010. The specification does not give a written description as to the genetic, morphological, or physiological composition of the claimed soybean plants or their non-S030010 parents. Furthermore, the specification fails to give any description as to the genetic composition of soybean variety S030010 and that of its parents. Since all soybean plants will vary in their genetic, morphological, and physiological composition, the genetic, morphological, and physiological background of the hybrid seed or plants derived from such a cross have not been adequately characterized.

Claim 13 is broadly drawn to any soybean plant, or parts thereof, produced by crossing soybean variety S030010 with another soybean plant. The specification does not give a written description as to the genetic, morphological, or physiological composition of the soybean plant or its non-S030010 parent. Since all soybean plants produced by this method will vary in their genetic, morphological, and physiological composition, the genetic, morphological, and physiological background of the hybrid seed or plants derived from such a cross have not been adequately characterized.

Claims 14-15 are broadly drawn to a method for producing a soybean variety S030010-derived soybean plant, and the plants derived from said method, by crossing soybean variety S030010 with a second plant, growing the seed from said cross, crossing the S030010-derived soybean plant with itself, growing the seed from said cross, and repeating the crossing and growing steps from 0-7 times to generate further soybean variety S030010-derived soybean plants. The claims seem to infer the use of

Art Unit: 1638

any soybean plant as the second soybean plant. The specification does not give a written description as the genetic, morphological, or physiological composition of the second soybean plant. Since all soybean plants will vary in their genetic, morphological, and physiological composition, the genetic, morphological, and physiological background of the hybrid seeds or plants derived from such a cross have not been adequately characterized.

Furthermore, in step (e) of claim 14 it states that the crossing and growing steps are to be repeated "0 to 7 times to generate further soybean variety S030010-derived soybean plants". The claim seems to infer that all plants from the cross will be harvested. Selfing a plant 0 to 7 times will give a different frequency of homozygous versus heterozygous plants with each selfing generation, with some plants having the genotype of the second soybean plant that was used in the cross. With each selfing generation heterozygosity decreases and homozygosity increases, so an F1 plant that is derived from the cross in claim 14 would have seeds that would produce plants with 25% homozygous S030010 genotypes, 50% heterozygous genotypes, and 25% homozygous "second plant" genotypes when using a single gene model. In contrast, after four generations of selfing, the same F1 plant would have seeds that would produce plants with 47% homozygous S030010 genotypes, 6% heterozygous, and 47% homozygous "second plant" genotypes when using a single gene model. Therefore, almost half of the harvested plants will possess the genotype of the "second plant" based on the interpretation of claim 14 and would not be a soybean variety S030010-derived soybean plant. Though selection in a breeding program at the fourth or greater

Art Unit: 1638

generation is well known in the art, there is no written description in the specification as to which trait or traits (phenotypic or genetic) are being selected for that would make a soybean variety S030010-derived soybean plant or even if these traits are dominant or recessive. Furthermore, there is no guidance as to the role epistasis or linkage drag may play in such a cross. Each generation of selfing will result in further rearrangements of dominant and recessive alleles at each locus. Thus each generation will comprise a multitude of individuals with different traits and different collections of traits, and no written description has been provided in the specification for these unknown plants or unknown genetic or morphological composition.

Claims 16-17 are broadly drawn to a method for producing a soybean variety S030010-derived soybean plant, and the plants derived from said method, by crossing a soybean variety S030010-derived soybean plant with a second plant, growing the seed from said cross, crossing the S030010-derived soybean plant with another soybean plant, growing the seed from said cross, and repeating the crossing and growing steps from 0-7 times to generate further soybean variety S030010-derived soybean plants. The claims seem to infer the use of any soybean plant as the second soybean plant. The specification does not give a written description as the genetic, morphological, or physiological composition of the S030010-derived soybean plant or the second soybean plant. Since neither of the parents are characterized and all soybean plants will vary in their genetic, morphological, and physiological composition, the genetic, morphological, and physiological background of the hybrid seeds or plants derived from such a cross have not been adequately characterized. Also, there is no written description as to the

Art Unit: 1638

derivation of the S030010-derived soybean plant in terms of how many generations it has been selfed (if any).

Furthermore, in step (e) of claim 16 it states that the crossing and growing steps are to be repeated "0 to 7 times to generate further soybean variety S030010-derived soybean plants". The claim seems to infer that all plants from the cross will be harvested. Selfing a plant 0 to 7 times will give a different frequency of homozygous versus heterozygous plants with each selfing generation, with some plants having the genotype of the second soybean plant that was used in the cross. With each selfing generation heterozygosity decreases and homozygosity increases, so an F1 plant that is derived from the cross in claim 16 would have seeds that would produce plants with 25% homozygous S030010 genotypes, 50% heterozygous genotypes, and 25% homozygous "second plant" genotypes when using a single gene model. In contrast, after four generations of selfing, the same F1 plant would have seeds that would produce plants with 47% homozygous S030010 genotypes, 6% heterozygous, and 47% homozygous "second plant" genotypes when using a single gene model. Therefore, almost half of the harvested plants will possess the genotype of the "second plant" based on the interpretation of claim 16 and would not be a soybean variety S030010-derived soybean plant. Though selection in a breeding program at the fourth or greater generation is well known in the art, there is no written description in the specification as to which trait or traits (phenotypic or genetic) are being selected for that would make a soybean variety S030010-derived soybean plant or even if these traits are dominant or recessive. Furthermore, there is no guidance as to the role epistasis or linkage drag

Art Unit: 1638

may play in such a cross. Each generation of selfing will result in further rearrangements of dominant and recessive alleles at each locus. Thus each generation will comprise a multitude of individuals with different traits and different collections of traits, and no written description has been provided in the specification for these unknown plants or unknown genetic or morphological composition.

Claims 20-22 are broadly drawn to a method for producing a soybean plant containing a transgene by crossing the soybean variety S030010 with a soybean plant of any genotype that has only been characterized as containing a transgene and the soybean plants or parts thereof. Claim 20 seems to infer the crossing of soybean variety S030010 with any soybean plant that contains any transgene, but the specification does not provide a written description of the genetic or morphological identity of the other soybean plant nor does it describe what type of transgene the other soybean plant is in possession of, with regard to sequence or encoded function. Furthermore, there is no written description that provides evidence of such plants having been created by the method, as is claimed in claim 22.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials". *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not description of that

Art Unit: 1638

material". Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus". Id.

See MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Given the failure of the specification to describe the claimed plant, methods of using it are also inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention. See the written description guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 4, 2001/ Notices: pp. 1099-1111.

Claims 7, 9-11, 13-17, 20-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way

Art Unit: 1638

as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 7 is broadly drawn to a soybean plant regenerated from the tissue culture of regenerable cells of soybean variety S030010 wherein said plant is "capable of" expressing the morphological characteristics of S030010. Since it is unclear whether the plant actually expresses these characteristics, the claim encompasses tissue-culture-derived somaclonal variants of soybean variety S030010, with mutations at one or more loci, which would not possess all the morphological and physiological traits that are inherent in soybean variety S030010. The specification, however, does not give a written description of such a regenerated plant as to its genetic, morphological, and/or physiological characteristics, therefore, one skilled in the art would not know how to use the claimed plant.

Claims 9-11, 13, 15, and 17 are broadly drawn to hybrid soybean plants derived from the crossing of soybean variety S030010 with any other soybean plant and the seed and plants derived from such a cross. Claims 9-10 are broadly drawn to any hybrid soybean seed or plant, respectively, produced from such a cross. Claim 11 is drawn to an F2 plant with, at most, 25% of its genome being derived from the soybean variety S030010. The claims seem to infer any soybean plant will be crossed with soybean variety S030010. The specification does not give any guidance as to the genetic, morphological, or physiological composition of the claimed soybean plants or their non-S030010 parents. Furthermore, the specification fails to provide any guidance as to the genetic composition of soybean variety S030010 and that of its parents. Since all

Art Unit: 1638

soybean plants will vary in their genetic, morphological, and physiological composition, it would be unpredictable as to the genetic, morphological, and physiological background of the hybrid seed or plants derived from such a cross. Thus one skilled in the art would not know how to use the plants or seeds.

Claim 13 is broadly drawn to any soybean plant, or parts thereof, produced by crossing soybean variety S030010 with another soybean plant. The specification does not give any guidance as to the genetic, morphological, or physiological composition of the soybean plant or its non-S030010 parent. Since all soybean plants produced by this method will vary in their genetic, morphological, and physiological composition, it would be unpredictable as to the genetic, morphological, and physiological background of the hybrid seed or plants derived from such a cross.

Claims 14-15 are broadly drawn to a method for producing a soybean variety S030010-derived soybean plant, and the plants derived from said method, by crossing soybean variety S030010 with a second plant, growing the seed from said cross, crossing the S030010-derived soybean plant with itself, growing the seed from said cross, and repeating the crossing and growing steps from 0-7 times to generate further soybean variety S030010-derived soybean plants. The claims seem to infer the use of any soybean plant as the second soybean plant. The specification does not give any guidance as to the genetic, morphological, or physiological composition of the second soybean plant. Since all soybean plants will vary in their genetic, morphological, and physiological composition, it would be unpredictable as to the genetic, morphological,

Art Unit: 1638

and physiological background of the hybrid seeds or plants derived from such a cross.

Thus one skilled in the art would not know how to use said plants.

Furthermore, in step (e) of claim 14 it states that the crossing and growing steps are to be repeated "0 to 7 times to generate further soybean variety S030010-derived soybean plants". The claim seems to infer that all plants from the cross will be harvested. Selfing a plant 0 to 7 times will give a different frequency of homozygous versus heterozygous plants with each selfing generation, with some plants having the genotype of the second soybean plant that was used in the cross. With each selfing generation heterozygosity decreases and homozygosity increases, so an F1 plant that is derived from the cross in claim 14 would have seeds that would produce plants with 25% homozygous S030010 genotypes, 50% heterozygous genotypes, and 25% homozygous "second plant" genotypes when using a single gene model. In contrast, after four generations of selfing, the same F1 plant would have seeds that would produce plants with 47% homozygous S030010 genotypes, 6% heterozygous, and 47% homozygous "second plant" genotypes when using a single gene model. Therefore, almost half of the harvested plants will possess the genotype of the "second plant" based on the interpretation of claim 14 and would not be a soybean variety S030010-derived soybean plant. Though selection in a breeding program at the fourth or greater generation is well known in the art, there is no guidance in the specification as to which trait or traits (phenotypic or genetic) are being selected for that would make a soybean variety S030010-derived soybean plant or even if these traits are dominant or recessive. Furthermore, there is no guidance as to the role epistasis or linkage drag may play in

Art Unit: 1638

such a cross. Each generation of selfing will result in further rearrangements of dominant and recessive alleles at each locus. Thus each generation will comprise a multitude of individuals with different traits and different collections of traits, and no written description has been provided in the specification for these unknown plants or unknown genetic or morphological composition. Therefore, one skilled in the art would not know how to use said progeny plants.

Claims 16-17 are broadly drawn to a method for producing a soybean variety S030010-derived soybean plant, and the plants derived from said method, by crossing a soybean variety S030010-derived soybean plant with a second plant, growing the seed from said cross, crossing the S030010-derived soybean plant with another soybean plant, growing the seed from said cross, and repeating the crossing and growing steps from 0-7 times to generate further soybean variety S030010-derived soybean plants. The claims seem to infer the use of any soybean plant as the second soybean plant. The specification does not give any guidance as to the genetic, morphological, or physiological composition of the S030010-derived soybean plant or the second soybean plant. Since neither of the parents is characterized, and all soybean plants will vary in their genetic, morphological, and physiological composition, it would be unpredictable as to the genetic, morphological, and physiological background of the hybrid seeds or plants derived from such a cross. Therefore, one skilled in the art would not know how to make or use the invention. Also, there is no guidance provided as to the derivation of the S030010-derived soybean plant in terms of how many generations it has been selfed (if any).

Art Unit: 1638

Furthermore, in step (e) of claim 16 it states that the crossing and growing steps are to be repeated "0 to 7 times to generate further soybean variety S030010-derived soybean plants". The claim seems to infer that all plants from the cross will be harvested. Selfing a plant 0 to 7 times will give a different frequency of homozygous versus heterozygous plants with each selfing generation, with some plants having the genotype of the second soybean plant that was used in the cross. With each selfing generation heterozygosity decreases and homozygosity increases, so an F1 plant that is derived from the cross in claim 16 would have seeds that would produce plants with 25% homozygous S030010 genotypes, 50% heterozygous genotypes, and 25% homozygous "second plant" genotypes when using a single gene model. In contrast, after four generations of selfing, the same F1 plant would have seeds that would produce plants with 47% homozygous S030010 genotypes, 6% heterozygous, and 47% homozygous "second plant" genotypes when using a single gene model. Therefore, almost half of the harvested plants will possess the genotype of the "second plant" based on the interpretation of claim 16 and would not be a soybean variety S030010-derived soybean plant. Though selection in a breeding program at the fourth or greater generation is well known in the art, there is no guidance in the specification as to which trait or traits (phenotypic or genetic) are being selected for that would make a soybean variety S030010-derived soybean plant or even if these traits are dominant or recessive. Furthermore, there is no guidance as to the role epistasis or linkage drag may play in such a cross. Each generation of selfing will result in further rearrangements of dominant and recessive alleles at each locus. Thus each generation will comprise a

Art Unit: 1638

multitude of individuals with different traits and different collections of traits, and no guidance has been provided in the specification for these unknown plants or unknown genetic or morphological composition.

Claims 20-22 are broadly drawn to a method for producing a soybean plant containing a transgene by crossing the soybean variety S030010 with a soybean plant of any genotype that has only been characterized as containing a transgene and the soybean plants or parts thereof. Claim 20 seems to infer the crossing of soybean variety S030010 with any soybean plant that contains any transgene, but the specification does not provide any guidance as to the genetic or morphological identity of the other soybean plant nor does it provide any evidence of such plants having been created by the method as is claimed in claim 22. Thus one skilled in the art would not know how to make or use such a plant.

While the introgression of single genes into plants for a desired trait is desirable and is well within the level of one skilled in the art, the state of the art teaches that it is unpredictable whether a gene or genes for conferring a phenotype in one plant genetic background may be transferred into the genetic background of another plant to confer the phenotype in said different plant. For example, Hunsperger et al. (US Patent No. 5,523,520) disclosed a specific gene trait in the genetic background of one plant which has been introgressed into the genetic background of another plant of the same species, that did not result in the expected transfer gene trait (see, column 3, lines 26-46). Kraft et al. (Theoretical and Applied Genetics 101:323-326, 2000) teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising

Art Unit: 1638

a single transferred trait and that effects are unpredictably genotype specific and loci dependent in nature. Kraft et al. teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is known about the plant breeding material, and therefore, is an unpredictable effect in plant breeding (see, page 323, column 1, lines 7-15). Eshed et al. (Genetics 143:1807-1817, 1996) teach that epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (see, pages 1815-1816). In a study conducted to determine the genetic analysis of brown stem rot resistance in soybean, Wilmot et al (Crop Sci. 29 :672-674, 1989) teach that epistasis does occur in soybean (see page 673, second column, third paragraph; page 674, Table 3 and Table 4). Dan et al (U.S. Patent No. 5,968,830, October 19, 1999) teach that transformation and regeneration of soybean is not reliable or predictable (see column 2, lines 22-34). Dan et al teach that the formation of shoots and roots only occurs in a small fraction of the cases and that successful transformation and regeneration are cultivar-specific.

Neither the instant specification nor the prior art provides evidence that such linkage disequilibrium, linkage drag, or epistatic effects are not common in soybean breeding materials, such that one or more genes can be transferred from one genetic background to another, wherein the resultant soybean progeny would either express the desired trait or maintain all of the other desirable S030010 genes and traits.

Given the lack of guidance in Applicant's specification regarding a multitude of non-exemplified hybrids, somaclonal variants, single gene conversions, the unpredictability of transferring said genes, and the breadth of the claims, one skilled in the art would not be able to make and/or use the inventions claimed without undue experimentations.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 18-19, and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 7, "is capable of expressing" does not clearly recite whether or not the characteristics are actually expressed. Replacement of "is capable of expressing" with "has" or "expresses" would overcome the rejection.

In claims 18 and 21, "transgene is selected from the group consisting of: herbicide resistance, insect resistance, and disease resistance" is confusing because a transgene confers a trait but is not equal to that trait. Replacement of "is" before "selected" with "confers a trait" would overcome the rejection.

Claim 18 is further indefinite in its recitation of "the soybean plant, or parts thereof, of claim 2, wherein the plant or parts thereof [has] been transformed". It is confusing to simultaneously characterize the non-transformed plant of claim 2 as being

Art Unit: 1638

transformed. Submission of a process claim reciting a process of transforming the soybean plant of claim 2 with a transgene conferring herbicide, insect, or disease resistance, followed by a product-by-process claim drawn to a transformed soybean plant produced by that method would overcome the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Boerma et al (Crop Sci. 41:920-921, 2001). The claims read on any soybean plant or parts thereof produced by the method of repeated crossing and growing steps from 0 to 7 times wherein the S030010-derived soybean plant is crossed with itself (claim 15) or crossed with another soybean plant (claim 17), thus the S030010 genetic material would be lost with each crossing-induced rearrangement of non-S030010 genetic material and the plants would be indistinguishable from any other soybean plant. The claimed method of making the plant would not confer a unique property to the resultant non-S030010 soybean plant.

Boerma et al teach soybean plants derived from crossing two soybean varieties (see entire document).

Art Unit: 1638

The soybean plant taught by the prior art differs from the claimed soybean plant only in their method of making, namely by the use of backcrossing in the prior art. However, the method of making the claimed soybean plant would not distinguish it from the prior art soybean plant. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products. See *In re Best*, 195 USPQ 430, 433 (CCPA 1997), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

Claims 1-14, 16, and 18-22 are deemed free of the prior art, given the failure of the prior art to teach or suggest an exemplified soybean variety which possesses a unique genetic complement and unique collection of traits as that of soybean variety S030010.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson, Ph.D. whose telephone number is

Art Unit: 1638

571-272-2918. The examiner can normally be reached on Monday - Friday 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, Ph.D. can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 17, 2004

KOR

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180

1638
David T. Fox